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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,155	12/15/2003	Nicholas A. Scusa	SCEUSA3A	2090
1444	7590	05/05/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,155	SCEUSA, NICHOLAS A.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/2006 has been entered.

Claims 1-11 and 13-14 are now pending in this application.

Claims 4-5 and 13 stand withdrawn from further consideration as being directed to non-elected subject matter. Claims 1-3, 6-11 and 14 will presently be examined *to the extent* that they read on the elected subject matter of record, i.e. Group I, wherein the animal to be treated suffers from an autoimmune disease which causes secretions and eruptions via the calcium cascade.

The Examiner again notes for the record that a method of inhibiting the calcium cascade comprising administering to an animal in need of treatment for the bullous form of impetigo an effective amount of mixture of zinc and copper metal ions (originally elected species) to block the calcium cascade is deemed to be allowable. The examination of the claims shall now continue with an expanded species scope, i.e. zinc or copper as the metal ion species.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-11 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for metal ions that have antimicrobial activity, which are administered to an animal that has a condition with an underlying or concomitant microbial etiology, such as for example the bullous form of impetigo, does not reasonably provide enablement for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims:

The claims are directed to a broadly defined mechanism (inhibit the calcium cascade) by which any animal suffering from an autoimmune disease which causes secretions and eruptions via the calcium cascade is effectively treated. It is not stated in the claims whether the secretions and eruptions are internal or external. The claims are extremely broad as shown below.

Diseases encompassed	Active agents	Mode of administration
<p>The elected invention is treating an animal suffering from an "autoimmune disease which causes secretions and eruptions via the calcium cascade."</p> <p>The specification only mentions the bullous form of impetigo.</p> <p>Other diseases could include lupus, scleroderma, inflammatory bowel diseases, psoriasis, autoimmune hepatitis, bullous pemphigoid, rheumatoid arthritis, and many other diseases.</p>	<p>Claim 1: "at least one pharmaceutically acceptable polyvalent metal ion that blocks the calcium cascade"</p> <p>Claim 2: Zn, Cu, Mg, Mn, Fe, Al, mixtures thereof</p> <p>Note, claims that are not as specific as claim 2 read on numerous polyvalent metal ions such as scandium, titanium, yttrium, technetium, molybdenum, tungsten and platinum.</p>	<p>Claim 1: not specified</p> <p>Claim 6: through the mouth to the nasal cavity</p> <p>Claim 7: through the mouth into the nasal cavity</p>

The state of the art in treating various autoimmune diseases is that such diseases are some of the most difficult diseases to treat. There is no common treatment that is effective for the many different types of autoimmune diseases. Here, the diseases encompassed are greatly divergent and are not known to be treated with one common type of medicine.

Even though the relative skill of those in the art is quite high given the medical degree necessary to practice medicine and treat patients with serious conditions as the above discussed autoimmune diseases, the unpredictability in the art is also quite high

due to the inability of science to find an effective treatment for the individual diseases, let alone a common treatment for all such diseases.

Unpredictability related to nasal or mouth-nasal cavity modes of administration is even higher. For example, impetigo is an infection of the skin. The claims read on nasally administering metal ions, or delivering metal ions across the mucous membranes of the mouth into the nasal cavity. In addition to the unpredictability involved for the reasons stated above, further unpredictability would result from such indirect administration of the metal ions.

In this context, the provided specification direction or guidance is quite sparse. Even though the same broad language as the claim language is used throughout the specification to describe the invention, no specific objective experimental result is provided to show that the metal ions of the invention, delivered via the nasal cavity or otherwise, would treat an animal "suffering from an autoimmune disease which causes secretions and eruptions via the Calcium cascade." Given the state of the art, the variety of divergent diseases encompassed by the claims, and the other factors discussed above, in the absence of any working examples one skilled in the art would be faced with undue experimentation in order to practice the invention to the full extent claimed.

Therefore, the claims are rejected as lacking in adequate enabling support.

Applicant's amendments and arguments relative hereto, filed on 2/13/2006, have been given due consideration but were deemed unpersuasive. Applicant argues that the claims are not directed to treating all autoimmune disease, but to treating only those autoimmune diseases that cause secretions and eruptions via the calcium cascade. Applicant cites numerous references to show that calcium cascade is involved in autoimmune diseases. However, such argument and evidence fail to counter the Examiner's position as set forth above. As mentioned previously, the scope of the claims are not limited to secretions and eruptions which are only external. Internal eruptions are reasonable to expect for most autoimmune diseases such as lupus and autoimmune hepatitis, which are discussed above. Further, the claims still read on an extremely broad group of metals, such as scandium, titanium, yttrium, technetium, molybdenum, tungsten and platinum. It remains the Examiner's position that for diseases as diverse and unrelated as autoimmune disease of the instant elected and examined invention, one skilled in the art would be faced with undue experimentation in order to practice the invention to the full extent claimed.

For these reasons, this ground of rejection must be maintained.

It is noted for the record that the Examiner and Ms. Kornbau discussed on 4/26/2006 possible claim amendments to potentially overcome the ground of rejection set forth above. Ms. Kornbau informed the Examiner on 4/27/2006 that applicant does

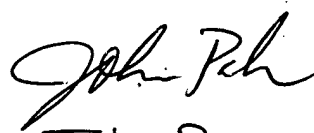
not intend to pursue this application. However, this Office action was necessary because a case (filed as RCE) cannot become abandoned unless the statutory period for reply to an Office action has elapsed (RCE has no outstanding Office action to reply to) or an express abandonment has been filed. Since an express abandonment was not filed, this RCE case can only be abandoned after an Office action has issued and the statutory period for reply has expired. An Office action is therefore issued herein.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is (571)272-0620. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on (571)272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.


John Pak
Primary Examiner
Technology Center 1600